DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

M3155n

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

May 11, 2000

WARNING LETTER
CHI-18-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Doug Rempel
Vice President of Sales/Marketing
International Imaging Electronics, Inc.
881 Remington Blvd.
Bolingbrook, IL 60440-4932

Dear Mr. Rempel:

During an inspection of your establishment located in Bolingbrook, IL, from March 6 to March 10, 2000, our investigator, Tamara Brey, determined that your establishment manufactures medical imaging electronic equipment such as multiformat cameras. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed. For example, your firm released for distribution three MP 4000 Series II Compact Video Imagers (MP 4600-2A-X) without the Final Quality Control Checkoff activities that are required by the procedure entitled, "MP4000-2A Series Checkoff Sheet, part number 003-20011-01, Rev. C," dated May 2, 1997.

2. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency, according to established procedures, to ensure the quality system satisfies the requirements of the Quality System Regulations and your firm's established quality policy and objectives. For example, your firm's "Management Responsibility Procedure, No. 006-00002-00 Rev. A," dated April 14, 1997, states that management will conduct a yearly Quality System Review Meeting. Our inspection determined your firm was not able to show that such a meeting was conducted within the last year.

3. Failure to conduct quality audits, to assure the quality system is in compliance with the established quality system requirements, and to determine the effectiveness of the quality system.

4. Failure to establish complaint handling procedures that ensure complaints are evaluated to determine whether the complaint represents an event that is required to be reported to FDA under the Medical Device Reporting Regulation.

5. Failure to establish adequate procedures to implement corrective and preventive action (CAPA). For example, your firm lacks written procedures that address the following:

    - Analysis of quality records, service records, consumer complaints, rejected in-house and vendor-supplied components and subassemblies;
    - Investigation of nonconformities;
    - Identification of action required to correct and prevent the recurrence of quality problems;
    - Verifying or validating corrective/preventive action;
    - Documentation of changes implemented as a result of CAPA procedures;
    - Submitting CAPA information to responsible individuals and management for review.

6. Failure to maintain complete complaint files. For example, your firm failed to document final actions and any replies to the complainant in the Year 1999 and Year 2000 complaint files.

7. Failure to establish adequate production and process control procedures. For example, your firm's "Engineering Change Control Procedure, No. 004-00004-0, Rev. A," dated March 20, 1996, does not require production or process procedures be verified or where appropriate, validated; and does not explain how the firm will determine when validation of such changes is appropriate.

The inspection revealed that your firm's electronic medical imaging products are misbranded within the meaning of Section 502(t)(2) in that procedures were not implemented and maintained as per 21 CFR Part 803, Medical Device Reporting (MDR). For example, your firm did not develop, implement, and maintain, as required by 21 CFR 803.17, written MDR procedures that address the following:

- How to timely and effectively identify, communicate, and evaluate MDR events;
- Transmit, in a timely manner, MDR Reports to the FDA, and;
- Documentation and record-keeping requirements.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We advise Federal agencies of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, we will not approve requests for Certificates to Foreign Governments until your firm corrects violations related to the subject devices and we verify your corrections. Once we verify your corrections we notify Federal agencies that may be considering the award of contracts.

We acknowledge that you firm responded by letter, dated March 31, 2000, to our investigator's FDA-483. We do not consider your response adequate because of the following:

Observation 1. Your response did not include corrective actions to prevent the deficiencies listed in this observation from recurring.

Observation 2. Your response did not include corrective actions to prevent the deficiencies listed in this observation from recurring.

Observation 3. Your response did not include corrective actions to prevent the deficiencies listed in this observation from recurring.

Observation 4. We are not able to evaluate the adequacy of the Medical Device Reporting Procedure (006-0010-00). Please submit a copy of the procedure.

Observation 5. Your response failed to show how the procedures you listed ("Product Complaint Procedure 006-00010-00" and "procedures dealing with EAR and ECO's") meet the requirements of procedures for corrective and preventive action as stated in the Quality System Regulation, Section 820.100, Corrective and Preventive Action. For example, your response does not show how the firm's procedures specify how to analyze processes, work operations, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Your firm failed to document errors or deficiencies that occurred on the manufacturing floor (equipment, personnel, and/or raw material failures) that cause non-conforming in-process product. For example, our investigator observed that non-conforming in-house assemblies (e.g. printed circuit boards, lenses) did not undergo your "Material Returns Bulletin (MRB) procedure, 005-00014-00, Rev. A."

Your statement, "This is a very small company (21 employees) everyone knows what quality issues we are dealing with," fails to describe how your procedures ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring product quality or preventing quality problems.

Furthermore, your response fails to address how your firm intends to prevent the deficiencies listed in this observation from recurring.

Observation 6. Your response did not include corrective actions to prevent the deficiencies listed in this observation from recurring.

Observation 7. We were not able to evaluate this corrective action because you did not submit a copy of the procedure for our review. Please submit a copy of the updated Engineering Change Order Procedure.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

In order to facilitate FDA in making the determination that corrections to the deviations from the Quality System Regulation have been made and thereby, enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts for medical devices, and to resume Certificates to Foreign Governments for medical devices manufactured at your facility located in Bolingbrook, IL, please submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device Quality System Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment, located in Bolingbrook, IL, has initiated and completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections should be submitted to this office on the following dates:

- Initial certifications by consultant and establishment: November 15, 2000 (or sooner)

- Subsequent certifications of updated audits and corrections: November 15, 2001
  November 15, 2002

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer.

Sincerely yours,

\s\
Raymond V. Mlecko
District Director
Chicago District